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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,653	10/10/2001	Andrew D. Bicek	760-49	9912

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EXAMINER

NGUYEN, VI X

ART UNIT PAPER NUMBER

3731

DATE MAILED: 12/22/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/974,653

Applicant(s)

BICEK ET AL.

Examiner

Victor X Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 and 25-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 5) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 6) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3. 6) ☐ Other: _____

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DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a stent, classified in class 623, subclass 1.12.
- II. Claims 8-16, drawn to a method of preparing a covered stent, classified in class 623, subclass 1.23.
- III. Claims 17-27, drawn to a covered stent, classified in class 623, subclass 1.13.
- IV. Claims 28-38, drawn to a method of preparing a covered stent, classified in class 600, subclass 36.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-IV are related as product and process for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the product as claimed can be used to practice another and materially different process. (MPEP § 806.05(h)). In this case the product as claimed can be used to practice another and materially different process, such as using a device to dissect tissue along vessel. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as

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claimed because the covered stent as claimed in the combination does not require to have a support stent as claimed in the subcombination. The subcombination has separate utility such as a system used to support or maintain the patency of the vessel (class 623/1.13). Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different sub- classification, restriction for examination purposes as indicated is proper.

Inventions III and IV are related as product and process for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the product as claimed can be used to practice another and materially different process. (MPEP § 806.05(h)). In this case the method as claimed can be used to practice another and materially different product, such as using a device to dissect tissue along vessel. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

2. The application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1 Figs 1-4

Species 2 Fig. 5

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

A telephone call was made to Mr. Ludomir A. Budzyn on 12/02/2003 to request an oral election to the above restriction requirement, an election was made **without traverse** to prosecute the invention of Group III, Species II in fig. 5. It would appear that claims 17-24 relate to Species II in fig. 5. Claims 1-16, 25-27 and 28-38 are drawn to Species I. Therefore, non-elected claims 1-16, 25-27 and 28-38 are withdrawn from further consideration.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-24 are rejected under 35 U.S.C. 102 (e) as being anticipated by Davila et al (U.S. 6,296,661).

Davila et al disclose in figs 6-9, a device having all the limitations of claim 17, including: a stent (80) has a radially-expandable body; at least one support stent (60) and a sheath (104) come between the body. The support stent with no portions of the main stent is in contact with at-least the support stent.

Regarding claims 18-19, Davila et al disclose the support stent (60) is superelastic alloys (see col. 5, lines 24-32). The sheath (104) disposes radially outwardly of the stent.

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Regarding claims 21-22, Davila et al disclose the support stent has an axial length which is less than the axial length of the body (fig. 6, see col. 5, lines 21-25).

Regarding claims 23-24, Davila et al disclose sheath is selected from the group consisting of a polymeric/a biomaterial sleeve (see col. 9, lines 25-38). The sheath is also treated with a drug selected from the group consisting of biocompatible material (see col. 3, lines 4-25).

Claims 17 and 20 are rejected under 35 U.S.C. 102 (e) as being anticipated by Davila et al (U.S. 6,296,661).

Davila et al disclose in figs 6-9, a device having all the limitations of claim 17, including: a stent (60) has a radially-expandable body; at least one support stent (80) and a sheath (104) come between the body. The support stent with no portions of the main stent is in contact with at-least the support stent.

Regarding claim 20, Davila et al disclose the sheath (104) disposes radially inwardly of the stent.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 5,411,550 to Herweck

U.S. Pat. No. 6,224,626 to Steinke

U.S. Pat. No. 6,506,408 to Palasis

U.S. Pat. No. 5,618,299 to Khosravi

U.S. Pat. No. 5,733,328 to Fordenbacher

U.S. Pat. No. 6,206,888 to Bicek

U.S. Pat. No. 6,575,994 to Marin

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M).


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Victor X Nguyen
Examiner
Art Unit 3731

Vn ✓
December 06, 2003



MICHAEL J. MILANO
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